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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,356	05/09/2001	Martin A. Cheever	014058-009811US	1297
20350	7590	01/26/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 01/26/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/854,356	<b>Applicant(s)</b> CHEEVER ET AL.	
	<b>Examiner</b> MISOOK YU, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 113-125 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 116 is/are allowed.
- 6) ☒ Claim(s) 113, 114, 117-125 is/are rejected.
- 7) ☒ Claim(s) 115 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 113-125 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112, Maintained***

Claims 113, 114, and 117-125 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This new matter rejection is made due to the newly added limitation "at least 90% identity to SEQ ID NO:6" in base claim 113.

Applicant argues that the 96.5% sequence identity between SEQ ID NO:2 of the '445 patent and instant SEQ ID NO: 6 is obtained in a manner inconsistent with the description of the instant specification describes the concept of percent identity on page 9, lines 18-26; SEQ ID NO: 2 of '445 patent is a full length protein, not fusion protein; applicant also states that applicant is uncertain as to how the "query match " value of 96.5% was obtained; even if 96.5% sequence identity between SEQ ID NO:2 of the '445 patent and instant SEQ ID NO: 6 is properly obtained according to the instant specification, the limitation "HER-2/neu fusion protein comprises at least 90% identity to the instant SEQ ID NO:6" and definition of "HER-2/neu fusion protein" as a protein "consisting of a HER-2/new extracellular domain fused to a HER-2/new phosphorylation

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domain” are mutually exclusive; there is no requirement in MPEP Section 2163 that the genus defined by a new limitation in an amended claim should be completely overlap with the defined by pre-existing claim limitations.

These arguments have been fully considered but found unpersuasive because the newly added limitation “the Her-2/new fusion protein comprises at least 90% identity to SEQ ID NO:6” changes the scope of “HER-2/new fusion protein” that was not originally disclosed.

As for question of how the query match of 96.5% arrived, the instant specification at pages 10, lines 19 to page 11 line 12 discloses that Smith and Waterman algorithm and BLOSUM62 scoring matrix are contemplated for sequence similarity comparison purpose. The previously provided sequence alignment mailed on 5/9/05 at page 1, left column says that query match is arrived using protein search, using sw (Smith Waterman) model, and the scoring table of BLOSUM62 scoring matrix. The perfect score for the instant SEQ ID NO: 6 based on Smith and Waterman algorithm and BLOSUM62 scoring matrix is 5078 (again note the previously provided sequence alignment, page 1, left column heading “perfect score”). Comparing instant SEQ ID NO: 6 against SEQ ID NO: 2 of the ‘445 patent results in score of 4900 according to Waterman algorithm and BLOSUM62 scoring matrix described in the instant specification. Thus,  $4900/5078 \times 100\% = 96.5\%$ .

As for the question of re-drawing the property line of the claimed invention by a new limitation in a subsequence amendment, MPEP Section 2163 does not say applicant could re-draw the property boundaries using a new limitation in the claims, in

such as a way, a species that does not have a support in the original disclosure is encompassed in the newly drawn property boundary encompassed by the new limitation introduced during prosecution.

### ***Priority***

Applicant's claim for domestic priority under 35 U.S.C. 119(e) to Application No. 60/117,976, and under 35 U.S.C. 120 to Application No. 09/493,480, filed 05/09/2001 is acknowledged. However, the applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 113, 114, and 117-125 of this application. The two previous application do not contemplate the claimed invention is directed to method using a polypeptide comprising "at least 90% identity to SEQ ID NO:6". Therefore the filing date of the claims claim 113, 114, and 117-125 is the filing date of the instant application, i.e. 09 May 2001.

Applicant argues that priority to the earlier application should be granted based on the applicant argument stated in traversing new matter rejection above. However, the new matter rejection stands for reasons set forth above.

### ***Claim Rejections - 35 USC § 102, Maintained***

Claims 113, 114, 118, 119, and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by US PAT 5,869,445 (02 February 1999).

Claims 113, 114, 118, 119, and 121 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6, wherein the composition is in vaccine (claim 114), along

with physiologically acceptable carrier or diluent (claim 118), an oil-in-water emulsion, and an immunostimulatory substance (claim 121).

Applicant argues that the rejection should be withdrawn based on applicant argument stated in traversing new matter rejection above. However, the new matter rejection stands for reasons set forth above, and the priority not granted.

As stated in the previous Office action, US PAT 5,869,445 at columns 2, 15, and 16 teaches a method of inducing immune response using a composition, or a vaccine comprising a protein comprising at least 90% identity to instant SEQ ID NO:6 (i.e. SEQ ID NO:2, note the previously provided sequence alignment (and see how the 96.5% query match is arrived using Smith-Waterman algorithm), along with physiologically acceptable carrier or diluent, an oil-in-water emulsion, and an immunostimulatory substance.

***Claim Rejections - 35 USC § 103, Maintained***

Claims 113, and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over D US PAT 5,869,445 (02 February 1999) in view of WO 91/18926.

Claims 113, and 117 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6, wherein the protein is lapidated.

Applicant argues that the rejection should be withdrawn based on applicant argument stated in traversing new matter rejection above. However, the new matter rejection stands for reasons set forth above, and the priority not granted.

See 102(e) rejection above for what US PAT 5,869,445 teaches.

US PAT 5,869,445 does not teach the protein being lipidated.

However, WO 91/18926 teaches that lipidation to a protein ensures optimal presentation of an antigen.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to lipidate a protein to stimulate immune response with a reasonable expectation of success.

Claims 113, 119, 120, 122, 123, 124, 124 are rejected under 35 U.S.C. **103(a)** as being unpatentable over US PAT 5,869,445 (02 February 1999) in view of WO95/17210 (filed on 07/02/1996).

Claims 113, 119, 120, 122, 123, 124 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6 in combination with various art-known adjuvants (tocopherol; claim 122, 3D-MPL, QS21, or a combination of 3D-MPL and QS21; claim 123, 3D-MPL and QS21 in an oil-in water emulsion; claim 124, 3D-MPL, QS21 with tocopherol).

Applicant argues that the rejection should be withdrawn based on applicant argument stated in traversing new matter rejection above. However, the new matter rejection stands for reasons set forth above, and the priority not granted.

See 102(e) rejection above for what US PAT 5,869,445 teaches.

US PAT 5,869,445 does not teach the protein being the various adjuvants.

However, WO95/17210 teaches that tocopherol, 3D-MPL, QS21, or a combination of 3D-MPL and QS21, 3D-MPL and QS21 in an oil-in water emulsion are well known adjuvants before the effective filing date of the instant application. Note columns 1-4.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use known adjuvants to stimulate immune response with a reasonable expectation of success.

Claims 113, and 125 are rejected under 35 U.S.C. **103(a)** as being unpatentable over US PAT 5,869,445 (02 February 1999) in view of WO 96/02555.

Claims 113, and 125 are interpreted as drawn to method of inducing immune response using a composition comprising a protein comprising at least 90% identity to SEQ ID NO:6 in combination with CpG-containing oligonucleotides.

Applicant argues that the rejection should be withdrawn based on applicant argument stated in traversing new matter rejection above. However, the new matter rejection stands for reasons set forth above, and the priority not granted.

See 102(e) rejection above for what US PAT 5,869,445 teaches.

US PAT 5,869,445 does not teach CpG-containing oligonucleotides.

However, WO 96/20555 teaches (at column 26 lines 15-22) that CpG-containing Oligonucleotides had been known as immune stimulatory molecules before the instant application was filed.



Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use a known immune stimulatory molecules to stimulate immune response with a reasonable expectation of success.

***Allowable Subject Matter***

Claim 115 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 116 is allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

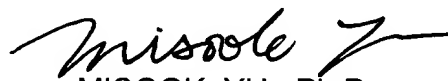
Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-

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272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MISOOK YU, Ph.D.  
Primary Examiner  
Art Unit 1642